PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.: 10/715,324	)	
Confirmation No. 5106	)	
Applicant: HUNT; THUDOR; WIXEY and McPHEE	)	
Filed: November 17, 2003	)	
For: HUMIDITY CONTROLLER	)	
Examiner: SANG YEOP PAIK	)	Attorney Docket No.:
Art Unit: 3742	)	1171/41475/56B/106/107-CIP

<u>RESPONSE TO EXAMINER'S ANSWER</u>

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant submits the following Reply Brief under 37 CFR §41.41. This Reply Brief is being submitted within two months of the mailing date of the Examiner's Answer.

This brief contains the following items under the following headings and in the order set forth below (37 CFR 41.37(c)):

I. Status of claims;

II. Grounds of rejection to be reviewed on appeal;

III. Argument; and

IV. Claims Appendix.

I. <u>STATUS OF THE CLAIMS (37 CFR 41.37(c)(1)(iii))</u>

Claims 1-14, 16-29, 31 and 32 stand finally rejected and are on appeal.

Claim 15 is objected to, based upon an alleged claim informality, and is not on appeal. Applicants submitted an amendment on December 5, 2005 in response to the Office Action of August 8, 2005 amending claim 15 to remove the claim informality. Therefore, claim 15 should be allowable.

Claim 30 is canceled.

II. GROUNDS OF REJECTION
TO BE REVIEWED ON APPEAL (37 CFR 41.37(c)(1)(vi))

1. Whether claims 1, 16, 17, 31 and 32 are patentable over the Examiner's rejection under 35 U.S.C. §102(b) as allegedly being anticipated by United States Patent No. 5,558,084 to Daniell et al.

2. Whether claims 3-7, 13, 14, 19-23 and 29 are patentable over the Examiner's rejection under 35 U.S.C. §103 as allegedly being unpatentable over Daniell et al.

III. ARGUMENT (37 CFR 41.37(c)(1)(vii))

1. Rejection under 35 U.S.C. §102(b) over U.S. Patent No. 5,558,084 to Daniell et al.

A. Claims 1, 17 and 32

The Examiner continues to assert that in the system disclosed by Daniell, temperature is a parameter relating to flow rate. However, the Examiner has admitted that it is possible to have high and low flow rate at high and low temperature.

The Examiner's argument is based upon the Ideal Gas equation PV=nRT. The Ideal Gas equation is only applicable to closed systems i.e. systems physically isolated from the outside world. In the system disclosed in Daniell, the humidifying chamber 3 is open, as it has two openings 4, 5. Openings 4 is a gas inlet and opening 5 is a gas outlet leading to a patient. These openings allow for the ingress and egress of gas to and from the humidifying chamber. The openings in the humidifying chamber described in Daniell mean that the ideal gas equation is not applicable to the system. At a steady temperature, the pressure of the gas in the humidifying chamber will always equal the gas pressure outside the chamber, as openings 4 and 5 allow the pressure to equalize. Accordingly, the temperature of the gas in the humidifying chamber has no bearing on the pressure of the gas in the humidifying chamber.

The pressure of the gas inside the humidifying chamber has no bearing on the flow rate through the apparatus. A pressure difference between the inside of the humidifying chamber and the outside of the humidifying chamber might lead to a net flow of gas into or out of the humidifying chamber. However, as stated above, the pressure inside the humidifying chamber will equalize with the pressure outside the humidifying chamber at any given temperature. The

pressure in the humidifying chamber at 20 degrees centigrade will be the same as the pressure in the humidifying chamber at 40 degrees centigrade i.e. atmospheric pressure, because of the presence of gas inlet 4. Without some external influence, such as the breathing of a patient, there would be no flow rate of gas through the system disclosed in Daniell. Furthermore, claims 1, 13, 17 and 31 all recite a parameter related to the flow rate of gas through the apparatus. Any movement of gas resulting from a difference in pressure between the inside of the humidifying chamber and the outside of the humidifying chamber in the system of Daniell would not result in a net flow of gas through the apparatus, only a net flow of gas into or out of the humidifying chamber. Given that the humidifying chamber in Daniell has an inlet and an outlet of approximately the same physical dimensions, the gas flow would be the same through both inlet 4 and outlet 5. Accordingly, there would be no net flow of gas through the apparatus.

The Examiner has suggested that the flow rate of gas in Daniell is controlled by controlling the temperature of the gas in a humidifying chamber. This is simply not the case. The temperature of the gas in the humidifying chamber of Daniell is controlled based on sensed ambient temperature to minimize condensation in the tube leading to the patient. The flow rate of gas through the apparatus is completely independent of the gas temperature and is not mentioned in Daniell.

B. Claims 16 and 31

In relation to claims 16 and 31, Applicant stands by their earlier remarks. The Examiner has noted in the reply that the Examiner considers that no audio alarm signal is itself an output indicative of correct connection between the conduit heater and the controller in the system of Daniell. However, no alarm signal might indicate a number of other things including a lack of

power to the system, or a fault in the alarm electronics. In Applicant's view, a lack of an alarm signal certainly cannot be read on to the requirement of the indicator of claim 16. Daniell simply does not teach an indication of correct connection between a conduit heater and a controller.

2. Rejection under 35 U.S.C. §103 over U.S. Patent No. 5,558,084 to Daniell et al.

A. Claims 3-7, 13, 14, 19-23 and 29

The Examiner's rejections to the dependent claims relating to particular control strategies continue to be vague and not based on any specific teaching in the prior art. For example, the Examiner suggests that the teaching of Daniell to change the temperature of the gas in the humidifying chamber with changes in ambient temperature makes it obvious to provide the controller with the steps of claim 3. Claim 3 recites steps for determining a parameter related to flow rate. The Examiner alleges that the parameter relating to flow rate in Daniell is gas temperature. The gas temperature in Daniell is simply measured by a temperature sensor. Notwithstanding the fact that Applicant completely disagrees that the temperature is related to flow rate, Daniell does not suggest or teach the use of a series of steps to determine the temperature of gas in the apparatus. All Daniell teaches is simply sensing temperature using a temperature sensor.

VI. CLAIMS APPENDIX (37 CFR 41.37(c)(1)(viii))

1. A breathing assistance apparatus adapted to deliver humidified gases at a desired level of humidity or at a desired temperature to a patient using open loop control comprising:

a humidifier having an electrical input power and capable of humidifying said gases up to a level of humidity prior to delivery to said patient, said level of humidity depending on said input power to said humidifier, and

a controller or processor configured or programmed to:

(a) determine a parameter relating to the flow rate of said gases through said apparatus;

(b) determine based on at least said parameter the required electrical power input to said humidifier to deliver said gases to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature; and

(c) supply as said input power to said humidifier a level of power substantially similar to said determined power input to said humidifier.

2. A breathing assistance apparatus as claimed in claim 1 further comprising:

a conduit for conveying said humidified gases from said humidifier to said patient

a conduit heater having an electrical input power, and being associated with said conduit wherein the gases flowing through said conduit are heated either directly or indirectly by said conduit heater whereby the level of heating depending on said input power to said conduit heater; and

an ambient temperature sensor providing an indication of the exterior temperature or said

controller or processor including a stored assumption used as an indication of the exterior temperature;

wherein instruction (b) further comprises determining based on at least said indication of the exterior temperature the required power input to said conduit heater to deliver said gases to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature;

and said instruction (c) further comprises supplying as said input power to said conduit heater a level of power substantially similar to said determined power input to said conduit heater.

3. A breathing assistance apparatus as claimed in claim 2 wherein said humidifier comprises a humidification chamber adapted to receive a volume of water and a water heater to heat said water to produce water vapour within said chamber in use, said gases passing through said water vapour in said chamber thereby being humidified, said instruction (a) further comprising:

i) energise said water heater to heat said water towards a first condition,

ii) determine a variable indicative of a property of said water heater and continually monitoring said variable, until said variable or said parameter indicates that said water has substantially reached said first condition,

iii) determine said parameter based on at least said variable and said indication of the external temperature.

4. A breathing assistance apparatus as claimed in claim 3 wherein the determination of said power to said humidifier in said instruction (b) is also based on said indication of the external temperature.

5. A breathing assistance apparatus as claimed in claim 3 wherein said controller or processor stores a further instruction:

(d) continuously monitor said parameter or said variable, and when a change in said parameter or said variable is greater than a first threshold said controller or processor reverts to said instruction (b) and when a change in said parameter or said variable is greater than a second threshold said controller or processor reverts to instruction (a).

6. A breathing assistance apparatus as claimed in claim 5 wherein said second threshold is based on the rate of change of said parameter with respect to time, and wherein when said rate of change goes over said second threshold said controller or processor reverts to said instruction (a).

7. A breathing assistance apparatus as claimed in any one of claims 3 to 6 further comprising:

a chamber sensor means providing an indication of the temperature of said water heater and providing an indication of the electrical power drawn by said water heater,

wherein said variable is indicative of said indication of the temperature of said water heater or said indication of the power drawn by said water heater.

8. A breathing assistance apparatus as claimed in claims 1 or 2 further comprising a gas supply adapted to supply gases to said humidifier at a required pressure and resulting flow rate.

9. A breathing assistance apparatus as claimed in claim 8 wherein said gas supply provides an output signal representative of the level of electrical input to said gas supply, said signal being supplied to said controller or processor and from which the flow rate of said humidified gases is determined.

10. A breathing assistance apparatus as claimed in claim 8 wherein said gas supply comprises a fan driven by a variable speed electric motor.

11. A breathing assistance apparatus as claimed in claim 10 wherein said estimate of the flow rate of said humidified gases is based on the current drawn by said variable speed motor.

12. A breathing assistance apparatus as claimed in claims 1 or 2 further comprising a gases flow rate sensor from which said estimate of the flow rate of said humidified gases is determined directly.

13. A breathing assistance apparatus adapted to deliver humidified gases at a desired level of humidity or at a desired temperature to a patient comprising:

a humidifier having an electrical input power and capable of humidifying said gases up to a level of humidity prior to delivery to said patient, said level of humidity depending on said input power to said humidifier,

a conduit for conveying said humidified gases from said humidifier to said patient, and

a controller or processor including stored instructions to:

(a) determine a parameter relating to the flow rate of said gases through said apparatus;

(b) determine based on at least said parameter the required electrical power input to said humidifier to deliver said gases to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature;

(c) supply as said input power to said humidifier a level of power substantially similar to said determined power input to said humidifier;

(d) continuously monitor said parameter and when a change in said parameter is greater than a first threshold said controller or processor reverts to said instruction (b) and when a change in said parameter is greater than a second threshold said controller or processor reverts to instruction (a).

wherein if said change in said parameter indicates a decrease in flow a relatively short delay is caused before said controller or processor reverts to said instruction (b) and if said change indicates an increase in flow a relatively long delay is caused before said controller or processor reverts to said instruction (b).

14. A breathing assistance apparatus as claimed in claim 13 further comprising:

a chamber sensor means providing an indication of the temperature of said water heater and providing an indication of the electrical power drawn by said water heater,

wherein said variable is indicative of said indication of the temperature of said water heater or said indication of the power drawn by said water heater.

15. A breathing assistance apparatus adapted to deliver humidified gases at a desired level of humidity or at a desired temperature to a patient comprising:

a humidifier having an electrical input power, a humidification chamber adapted to receive a volume of water and water heater to heat said water to produce water vapour within said chamber in use, said gases passing through said water vapour in said chamber thereby being humidified, said humidifier capable of humidifying said gases up to a level of humidity prior to delivery to said patient, said level of humidity depending on said input power to said humidifier, including

a conduit for conveying said humidified gases from said humidifier to said patient, and

chamber sensing means providing an indication of the temperature of said water heater and providing an indication of the electrical power drawn by said water heater,

a controller or processor including stored instructions to:

(a) energise said water heater to heat said water towards a first condition, determine a variable indicative of a property of said water heater and continually monitor said variable, until said variable indicates that said water has substantially reached said first condition, and determine a parameter relating to the flow rate of said gases through said apparatus based on at

least said variable and said indication of the external temperature;

(b) determine based on at least said parameter the required electrical power input to said humidifier to deliver said gas to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature;

(c) supply as said input power to said humidifier a level of power substantially similar to said determined power input to said humidifier;

wherein said variable is indicative of said indication of the temperature of said water heating means or said indication of the power drawn by said water heating means and said parameter is defined as the value of said power drawn by said water heater divided by said temperature of said water heater.

16. A breathing assistance apparatus adapted to deliver humidified gases at a desired level of humidity or at a desired temperature to a patient comprising:

a humidifier having an electrical input power capable of humidifying said gases up to a level of humidity prior to delivery to said patient, said level of humidity depending on said input power to said humidifier,

a conduit for conveying said humidified gases from said humidifier to said patient, and

a conduit heater having an electrical input power, and being associated with said conduit wherein the gases flowing through said conduit are heated either directly or indirectly by said conduit heater wherein the level of heating depends on said input power to said conduit heater;

a controller or processor which supplies said input power to said humidifier and said conduit heater, and provides a control output indicative of said conduit heater being correctly

connected to said controller or processor and capable of operating in according within predefined limits; and

a connector to electrically connect said controller or processor and said conduit heater and including an indicator in use connected to said control output, wherein when said conduit heater is correctly connected to said controller or processor and capable of operating in according within predefined limits said controller or processor energise said indicator.

17. A method of delivering humidified gas at a desired level of humidity or at a desired temperature to a patient using an open loop controlled humidifier comprising the steps of:

(a) determining a parameter relating to the flow rate of said gas through said humidifier;

(b) determining based on at least said parameter the required electrical power to said humidifier to deliver said gas to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature; and

(c) supplying a level of power to said humidifier substantially similar to said determined power.

18. A method as claimed in claim 17 further comprising the steps:

conveying said humidified gas to a patient;

heating the conveyed gas either directly or indirectly using a conduit heater; and

sensing or making an assumption of the exterior temperature;

wherein said step (b) further comprises determining based on at least said indication of

the exterior temperature the required power input to said conduit heater to deliver said gas to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature;

and wherein said step (c) further comprises supplying as said input power to said conduit heater a level of power substantially similar to said determined power input to said conduit heater.

19. A method as claimed in claim 18 wherein said humidifier comprises a humidification chamber adapted to receive a volume of water and water heater to heat said water to produce water vapour within said chamber in use, said gas passing through said water vapour in said chamber thereby being humidified, said step (a) further comprising:

i) energising said water heater to heat said water towards a first condition,

ii) continuously monitoring or a variable indicative of a property of said water heater, until said variable or indicates that said water has substantially reached said first condition,

iii) determining a parameter based on at least said variable and said indication of the exterior temperature.

20. A method as claimed in claim 19 wherein the determination of said power to said humidifier in said instruction (b) is also based on said indication of the external temperature.

21. A method as claimed in claim 20 further comprising the step:

(d) continuously monitoring said parameter or said variable, and when a change in said parameter or said variable is greater than a first threshold revert to step (b) and when a change in said parameter or said variable is greater than a second threshold revert to step (a).

22. A method as claimed in claim 21 further comprising the step of when said rate of change or said change in said parameter indicates a decrease in flow pausing for a first delay before said controller or processor reverts to step (a) and when said rate of change or said change indicates an increase in flow pausing for a second delay before reverting to step (a), said second delay being longer than said first delay.

23. A method as claimed in claim 22 wherein said second threshold is based on the rate of change of said parameter or said variable with respect to time, and further comprising the step of when said rate of change goes over said second threshold reverting to step (a).

24. A method as claimed in claim 17 further comprising the step of supplying gas to said humidifier at a required pressure and resulting flow rate.

25. A method as claimed in claim 24 further comprising the step of determining the level of electrical power required to supply said gas at a required pressure and resulting flow rate, from which the flow rate of said humidified gas is determined.

26. A method as claimed in claims 25 wherein said gas is supplied by a fan driven by a variable speed electric motor.

27. A method as claimed in claim 26 wherein said estimate of the flow rate of said humidified gas is based on the current drawn by said variable speed motor.

28. A method as claimed in claim 26 wherein said estimate of the flow rate of said humidified gas is determined directly from a gas flow rate sensor.

29. A method as claimed in claim 19 further comprising the step of:

sensing the temperature of said water heater and providing an indication of the electrical power drawn by said water heater,

wherein said variable is indicative of the temperature of said water heater or said indication of the power drawn by said water heater.

30. (Canceled)

31. A method of connecting a conduit heater within a conduit to a humidifier comprising the steps of:

providing an electrical connection between said conduit heater and said humidifier; and

indicating whether conduit is being correctly connected and capable of operating in according within predefined limits.

32. A breathing assistance apparatus adapted to deliver humidified gas at a desired level of humidity or at a desired temperature to a patient using open loop control comprising:

humidifier means having an electrical input power and capable of humidifying said gas up to a level of humidity prior to delivery to said patient, said level of humidity depending on said input power to said humidifier,

means for determining a parameter relating to the flow rate of said gas through said apparatus;

means for determining based on at least said parameter the required electrical power input to said humidifier to deliver said gas to said patient at a level of humidity or at a temperature substantially similar to said desired level of humidity or said desired temperature;

means for supplying as said input power to said humidifier a level of power substantially similar to said determined power input to said humidifier.

This Response is respectfully submitted by:

Attorneys for Applicant/Appellant

Date: Dec. 1, 2006

By: Raiford A. Blackstone

Raiford A. Blackstone, Jr., Reg. No. 25,156
Linda L. Palomar, Reg. No. 37,903

TREXLER, BUSHNELL, GIANGIORGI,
BLACKSTONE & MARR, LTD.
105 West Adams Street
Suite 3600
Chicago, Illinois 60603-6299
(312) 704-1890

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